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09/512,593	02/23/2000	John W. Eaton	5050/651	3307

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/512,593

Applicant(s)

EATON ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 060305.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-19, 24-26, 55-62 and 66 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 20-23, 27-32, 35-40, 63, 64, 67, 68 and 75-88 is/are rejected.
- 7) ☒ Claim(s) 6, 12-14, 33, 34, 41-54, 65 and 69-74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The status of co-pending cases mentioned in cols. 4 and 7 of the specification should be updated.

Appropriate correction in re-issue amendment format is required.

[Parenthesized claim numbers found below pertain to the specific claim or claims being addressed by the immediately preceding argument.]

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 75-79 are again rejected under 35 USC103(a) as obvious based upon Bechai et al or linuma, in either case further in view of Seward et al (US5699805 of record) and/or Eberle et al (US538037 of record).

Bechai et al as well as linuma teach inclusion of both endfire 50 or A and sidefire 48 or B arrays at the tip of a catheter-like probe for driving selective displays. Whereas they do not respectively refer to their device as a catheter, it would have been obvious in view of Seward et al which teaches an ultrasound catheter including as plurality of (longitudinal) linear phased arrays at the distal end that a device such as in Bechai et al is in fact a catheter of esophageal-inserted type. In the alternative, it would have been obvious in view of Eberle et al to provide such end or side-fire arrays on an ultrasound (intravascular) catheter since these were also known to provide scan information from within vessel walls. (Claims 1, 75). Seward et al makes clear in col. 6 lines 11 – 22 that the disclosed catheter is usable inside the blood vessel or inside a cavity such as the esophagus whereupon it would have reasonably been called a transesophageal imaging catheter.

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Eberle et al teaches that when arrays are adapted for an intravascular catheter the imaging catheter may be made as small as 1mm diameter, see col. 11 lines 65-68..

(Claims 76-79)

Claims 2 – 4, 27-29, 35-36 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, or in the case of Bechai et al further in view of linuma (US5450850). Whereas only Seward et al refer to their array as a phased (and also planar) array, it would have been obvious in view of linuma Figs. 15-16 and col. 13 lines 11 – 28 to provide phasing to both a longitudinal linear and a generally radial or annular array on the tip of a (catheter or catheter-like) probe since this allows resolution for an image in two geometries. (Claim 2).

Both Seward et al and linuma teach linear arrays oriented such that the scan azimuth is parallel to the longitudinal array axis. (Claim 3).

In linuma for example the reversal of the two arrays proximal to distal would be inherently obvious since the perpendicular array orientations merely provide three-dimensional information from closely adjacent positions which is achievable in either order of array, proximal to distal. (claims 4,35-36).

Claims 5 and 30-31, 38-40 and 67 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 2, 35 above, and further in view of Kitney et al (US5081993 of record) since whereas the former are silent as to the use of an additional radial array, Kitney et al Fig. 4 vs Fig. 3 details that an additional radial array may be added to a catheter device in order that 3D scanning may be rapidly

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had by energizing sub-arrays in more than one plane simultaneously. (Claims 5, 30-31, 38-40).

Kitney et al further teaches that a position sensor may be included in such a catheter tip, see col. 12 lines 31-64. (Claim 67).

Claim 68 is again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 67 above, and further in view of Martinelli (US4821731).

Whereas Kitney et al teach a radiographic and a spark-gap position-sensing alternative, it would have been obvious in view of Martinelli et al to provide a magnetic position sensing tip in order to provide the position location called for in Kitney et al since this was a well-known sensor alternative. (Claim 68).

Claims 10, 32, 37 are again rejected under 35 USC 103(a) as obvious based upon the references as applied against claims 2 or 5 or 36 above, and further in view of Fujio et al (US5471988)..

Whereas the former do not discuss forward curving of the linear array around the catheter tip, it would have been obvious in view of Fujio et al Fig.55A element 347 to do so since this would provide the viewing array to forward look in linuma while allowing a blunt rounded tip penetration profile in Bechai et al . (Claims 10, 32, 37).

Claims 7 – 9, 11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over linuma and Seward et al. Both references teach use of plural arrays on the distal tip of a catheter-like device with displays for viewing the scans therefrom; in Inuma a combined radial and longitudinal phased array pair are taught.. Since

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Seward et al phased array catheters as suitable for intravascular use while linuma teaches transmit and receive beamformers 13, 23 for association with phased longitudinal and radial arrays such as Figs. 15-1, either reference may serve as a base reference modified by the other. (Claims 7-9, 11).

Claims 20—23, 63-64 are again rejected under 35 U.S.C. 102(b) as obvious over linuma in view of Seward et al.

Since linuma computes ejection fraction based upon imaging of cardiac structure with a conventional extra-thoracic probe 16, the tomography-based aortic area determinations done by the dual linear and at least partly radial arrays of probe 121 are in effect part of a cardiac structure imaging method, whereupon Seward et al is merely relied upon to evidence that probe 121 of linuma would be designated a catheter. (claims 20-23, 63-64).

Claims 80, 83, 86 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kitney et al. Kitney et al is applied as above, namely as a teaching that a tip position-sensing system may either co-relate between imaging modalities or determine the position of the intravascular catheter probe. Kitney et al do not state that absolute position is determined, however position is relative or absolute in a sense of what is the system's reference, meaning that it would have been inherently obvious to consider the ultrasound image point of reference as the absolute point of reference against which other spatial distances are measured. (Claims 80, 83, 86).

Claims 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitney et al as applied to claim 80 above, and further in view of Martinelli et al which

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determines both position and rotational orientation, as the latter was applied to supplement Kitney et al above. (Claims 81, 82).

Claims 84 – 85 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kitney et al as applied to claim 83 above, and further in view of Bechai et al and Iinuma, since whereas the former is silent as to phased array use the latter indicate the usefulness of radial and/or phased arrays in forming multi-directional images and the need for beamforming to recover the image data of a phased array. (Claims 84, 85)..

Claims 87-88 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kitney et al as applied to claim 80 above, and further in view of Eberle et al.

Whereas the former is silent as to catheter size, it would have been obvious in view of the latter col. 11 lines 65-68 to manufacture the imaging catheter in the 1-4mm range so that coronary artery imaging may be effected.

Allowable Subject Matter

Claims 6, 12 –14, 33-34, 41 – 54, 65, 69 - 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15-19, 24-26, 55-62, 66 are allowed.

The offer filed on 2-23-2000 to surrender the original patent is again noted.

Patent citations provided on the accompanying PTO-892 show the designation of transesophageal imaging probes as catheter devices by those working in the art.

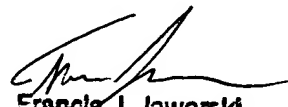
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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj


Francis J. Jaworski
Primary Examiner